REMARKS

Claims 1-3, 5, 6, 10-17, 21 and 23 are currently pending in the application. Applicants herein cancel claims 3, 5, 17, 22, and 23 without prejudice. Claims 1 and 10 are in independent form. Claim 1 has been amended to more clearly define "irregular blood flow" as "a blood flow restriction", similar to language in claim 10. No new matter has been added.

Applicants wish to express their appreciation for the courtesies extended Applicants' representative, Kenneth I. Kohn, during a personal interview conducted on January 29, 2008, with the Examiner and her Supervisor.

Claims 3 and 5 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite, and specifically because claim 3 recites "computing means for computing an algorithm...algorithm including estimating means" and the algorithm includes a physical system. In order to expedite prosecution, Applicants have canceled these claims without prejudice, rendering the rejection moot.

Claims 17, 22, and 23 stand rejected under 35 U.S.C. §101 as being directed to non-statutory subject matter. Specifically, the Office Action holds that claim 17 is drawn to an algorithm, which is saved on a computer readable medium; however, there is no transformation nor does the claim produce a tangible result. In order to expedite prosecution, Applicants have canceled these claims without prejudice, rendering the rejection moot.

Claims 1-3, 5-6, 10-17, and 22-23 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,710,164 to Levin, et al. in view of U.S. Patent No. 4,466,804 to Hino. Specifically, the Office Action holds that Levin, et al.

discloses a method and apparatus for continuously monitoring blood pressure during hemodialysis, upon detecting a decrease in a patient's blood pressure, the fluid extraction rate will be reduced; a programmed microprocessor is provided for controlling fluid extraction rates and blood pressure monitoring intervals, which is connected to an extracorporeal circuit, will automatically analyze the mean arterial blood pressure and heart rate of the patient at variable intervals for detecting the excessive removal of water from the patient being dialyzed and comparing the blood pressure and heart rate to a standard; if the patient's blood pressure remains below the systolic and/or diastolic low alarm limits, this is an indication of excessive water removal that can cause hypotension, and an audible alarm is activated to call for manual intervention or the device automatically reduces the ultrafiltration function of the dialysis machine and provides an untravenous infusiton of hypertonic saline; cabal/electronic communication which connect the display to the dialysis machine are used as means for communicating a warning when the mean arterial blood pressure or heart rate is off limits; the microprocessor is preprogrammed with high and low blood pressure and heart rate alarm limits which may be modified from an operator control panel, the microprocessor is also preprogrammed to detect deviation of blood pressure or heart rate from initial readings obtained and stored at the onset of dialysis. The Office Action holds that Levin, et al. fails to disclose that the automatic blood pressure monitoring system is an extracorporeal blood flow circuit, which is used to derive the intravascular blood pressure. The Office Action holds that Hino discloses an extracorporeal blood circulation system including a line for withdrawing the venous blood from the patient, a reservoir for the blood withdrawn, a blood supply line for sending out the blood from the reservoir to the artery of the patient, the blood supply pump is stopped when the arterial pressure of the patient measured is above a predetermined upper limit value, which the pump is driven when the arterial pressure has lowered to a level below a lower limit value. Therefore, the Office Action holds that it would have been obvious to use an extracorporeal blood pressure monitoring system

as taught by Hino instead of the automated blood pressure monitor of Levin, et al. in order to stop the dialysis machine if the blood pressure decreases as monitored in the catheter. Reconsideration of the rejection under 35 U.S.C. § 103(a), as being unpatentable over Levin, et al. in view of Hino, as applied to the claims is respectfully requested.

"Any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed"; however, that reason must be present for the combination to be obvious. *KSR Intern Co. v. Teleflex*, 127 S. Ct. 1727, 1742, U.S. (2007). This requirement was confirmed in *Takeda Chem. Indust., et al. v. Alphapharm*, No. 06-1329 (Fed. Cir. 2007).

As previously stated, Levin, et al. discloses a method and system for continuously monitoring patient heart rate and blood pressure during hemodialysis and for automatically controlling fluid extraction rate and/or dialysate sodium concentration in the event that blood pressure and/or heart rate indicate onset or impending onset of a patient hypotensive episode. There are three separate machines for performing these functions: an automated blood pressure monitor, an automated patient heart rate monitor, and the hemodialysis machine. The blood pressure monitor is essentially a device for measuring the patient's blood pressure based on readings from a blood pressure cuff placed around the patient's arm, i.e. a cuff that inflates and deflates automatically to read the diastolic and systolic blood pressure. This cuff is placed on the opposite arm from the access site used to extract and return the blood in the extracorporeal dialysis machine circuit. In other words, the device of Levin, et al. is using a standard blood pressure cuff that is part of all dialysis machines to monitor the patient's blood pressure. All blood pressure readings are performed on blood that is inside the patient, i.e. intravascular blood,

but not in proximity of the access site of the extracorporeal circuit. There are no extracorporeal blood readings used in the control algorithm. Pressure measurements made in the extracorporeal circuit by the dialysis machine are not used at any time in the control algorithm and neither is there any reason to do so. None of the required pressure measurements for the current patent application are taken with a device as disclosed by Levin, et al, nor is Levin patenting the cuff used to take blood pressure measurements.

Furthermore, Applicants point out that the Office Action's statement that the Levin, et al. device can provide "an indication of a potential stenotic lesion" is not stated anywhere in the referenced section of Col 2, lines 1-6 and 17-20. The Office Action continues stating that "The blood pressure monitor (14 of Levin), detects and estimates the intravascular blood pressure of the patient" and references Col 4, lines 18-22 of Levin, et al. The stated reference does not speak to this issue. However, wherever Levin, et al. does reference intravascular blood pressure, the patient's blood pressure is referenced, not the intravascular pressure in a specific site, i.e. the access site for the extracorporeal blood circuit of the dialysis machine.

The presently pending claims require a measurement and analysis of extracorporeal blood pressure, i.e. blood that is outside of the body in a vascular access port, in order to indicate irregular intravascular blood flow inside the body. The analysis of the extracorporeal blood pressure of the present invention provides a unique method of determining potential problems within the patient's intravascular blood stream within proximity of the access site for the dialysis circuit. The combination of Levin, et al. with Hino would still not arrive at the present invention. Simply making the Levin, et al. device extracorporeal does not allow for the required measurements to analyze irregular intravascular blood flow.

Also, one skilled in the art would have no reason to combine Levin, et al. with the teachings of Hino. Hino discloses a heart lung machine used during surgery to replace the function of the heart and lungs. It has nothing to do with dialysis or the detection of a blockage in an artery or a vein supplying an access site for dialysis. In Hino, central venous pressure (CVP) is maintained by allowing the blood to flow into an adjustable length of vertical tubing open to the atmosphere at one end. When the venous pressure forces blood above the level of the top of the tube, an optical detector senses the blood spilling over in a second tube and turns on a blood pump to remove more blood from the body and reduce CVP. In contradistinction, a dialysis circuit is a closed pressurized extracorporeal circuit where blood is removed from the arterial side of the access and returned to the venous side. The CVP measurements made during the use of the Hino device are used to regulate the central venous pressure about a set pressure point so that the machine does not malfunction. Critically, the CVP measurements are not used as a diagnostic tool to determine if a stenosis is developing in a vein or an artery.

Essentially, the device of Hino does not operate in the same manner as the present invention. In Hino, the venous pressure controls the input (taking blood out of the patient) and arterial pressure is used to detect the heart pulse to control the pulsating pump putting blood into the patient. In the present invention, venous pressure monitors the output (putting blood back into the patient from the dialysis machine) and arterial pressure monitors the blood taken out of the body. While Hino detects the CVP blood pressure, Hino does not detect irregular intravascular blood flow from measurement of extracorporeal blood pressure by performing the analysis required by the presently pending independent claims.

Since neither the cited references alone or in combination with knowledge in the art suggest the currently claimed invention, it is consequently respectfully

submitted that the claims are clearly patentable over the combination, even if the combination were to be applied in opposition to applicable law, and reconsideration of the rejection is respectfully requested.

The remaining dependent claims not specifically discussed herein are ultimately dependent upon the independent claims. References as applied against these dependent claims do not make up for the deficiencies of those references as discussed above, and the prior art references do not disclose the characterizing features of the independent claims discussed above. Hence, it is respectfully submitted that all of the pending claims are patentable over the prior art.

It is respectfully requested that the present amendment be entered in order to place the application in condition for allowance or at least in better condition for appeal. The application is placed in condition for allowance as it addresses and resolves each and every issue that remains pending. The amendments overcoming the rejections under 35 U.S.C. § 112 are made exactly as suggested by the Office Action. Further, the claims have been amended to more specifically define the invention while raising no new issues that would require any further searching. Rather, the amendments have been made in view of comments made in the Office Action that clearly distinguish the presently pending claims over the cited prior art. Hence, it is respectfully requested that the amendment be entered.

In view of the present amendment and foregoing remarks, reconsideration of the rejections and advancement of the case to issue are respectfully requested.

The Commissioner is authorized to charge any fee or credit any overpayment in connection with this communication to our Deposit Account No. 11-1449.

Respectfully submitted,

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CERTIFICATE OF ELECTRONIC FILING VIA EFS-WEB

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I hereby certify that this correspondence is being electronically filed with the United States Patent & trademark Office on the above date.

Connie Herty